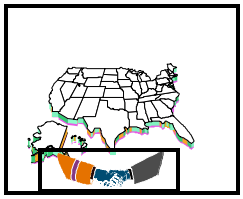

NELAC

NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE

On-site Assessment

July 24, 1996

TABLE OF CONTENTS

ON-SITE ASSESSMENT

| ***N O T E:*** ***Sections to be submitted by the On-site Assessment committee for vote at a later date are marked in the margins as in this note.***

3.0 ON-SITE ASSESSMENT

3.1 INTRODUCTION

The on-site assessment is an integral and requisite part of a laboratory accreditation program and will be one of the primary means of determining a laboratory's capabilities and qualifications. During the on-site assessment, the assessment team will collect and evaluate information and make observations which will be used to judge the laboratory's conformance with established accreditation standards.

It is essential that the on-site assessment conducted by any accrediting authority in the United States wishing to be recognized by the National Environmental Laboratory Accreditation Program be conducted in a uniform, consistent manner. Reasons for fostering this consistency include a need to assure the base quality of data coming from the laboratories; to allow more confident comparison of results generated by different laboratories; to facilitate reciprocity; and for the laboratory community to accept the accreditation standards.

This section describes the essential elements that are to be included in any acceptable on-site assessment and the qualifications and requirements for assessors.

The responsibility for promulgating and enforcing occupational safety and health standards rests with the U.S. Department of Labor. While it is not within the scope of the assessment team to evaluate all health and safety regulations, any obviously unsafe condition(s) observed should be described to the appropriate laboratory official and reported to the accrediting authority. The accreditation on-site assessment is not intended to certify that the laboratory is in compliance with any applicable health and safety regulations.

3.2 ON-SITE ASSESSMENT PERSONNEL

3.2.1 Training

The National Environmental Laboratory Accreditation Conference (NELAC) specifies the minimum level of education and training for assessors, including refresher/update training. The NELAC also develops standards for training requirements. The assessor training program will be developed and implemented by either accrediting authorities,

accrediting bodies, or other entities. All assessor training programs, must meet the NELAC standards.

Until such time as the NELAC has developed and published training requirements for laboratory assessors, each accrediting authority shall approve the training and experience requirements for each of its assessors (federal, state and/or third party).

When the NELAC has completed the development and promulgation of assessor training program standards, accrediting authorities, accrediting bodies, or other entities may petition the NELAP for approval of various formal training programs which meet the NELAC standards.

3.2.2 Basic qualifications

A laboratory assessor may work for a Federal, State, or a third party assessor body. An assessor must be an experienced professional and hold at least a B.S. degree in a basic science, or have equivalent education and experience in laboratory assessment or related fields.
Each assessor must also have satisfactorily completed an approved assessor training program and take periodic update/refresher training, as specified by NELAC. Each new candidate assessor must undergo training with a qualified assessor during four or more actual assessments until judged proficient by the accrediting authority.

3.2.3 Additional qualifications

In addition, the assessors must:

a) Be familiar with the relevant legal regulations, accreditation procedures, and accreditation requirements;
b) Have a thorough knowledge of the relevant assessment methods and assessment documents;
c) Be thoroughly familiar with the various forms of records described in Section 3.5.3 - Records Review;
d) Be thoroughly cognizant of data reporting, analysis, and reduction techniques and procedures;
e) Be technically conversant with the specific tests or types of tests for which the accreditation is sought and, where relevant, with the associated sampling and preservation procedures; and
f) Be able to communicate effectively, both orally and in writing.

3.2.4 Assessor qualification

Before an assessor can conduct on-site assessments, the individual must be qualified by an accrediting authority. Each assessor must sign a

statement before conducting an assessment certifying that no conflict of interest exists and any supporting information as required by the accrediting authority. Failure to provide this information will make the proposed assessor ineligible to participate in the assessment program.

3.3 FREQUENCY OF ON-SITE ASSESSMENTS

3.3.1 Frequency

Accrediting authorities must require a comprehensive on-site assessment of each facility that is accredited at least every two years. Assessments may be conducted more frequently for cause, at the option of the accrediting authority.

3.3.2 Follow-up assessments

In addition to routine assessments, assessors may need to conduct follow-up assessments at laboratories where a deficiency was identified by the previous assessment. These assessments may be, but are not necessarily limited to, determining whether a laboratory has corrected its deficiency(ies), or determining the merit of a formal appeal from the laboratory. When deficiencies are of such severity as to possibly warrant the downgrading of a laboratory's accreditation status, any follow-up assessment that is planned or conducted should be completed and reported within forty-five days after the original assessment.

Nothing in this section should be construed as requiring an accrediting authority to reassess a facility prior to taking a regulatory or administrative action affecting the status of the facility’s accreditation. Nothing in this section should be construed as limiting in any way the accrediting authorities ability to revoke or otherwise limit a laboratory’s accreditation upon the identification of such deficiencies as to warrant such action.

3.3.3 Changes in laboratory capabilities

The accrediting authority may also deem necessary an assessment when a major change occurs at a laboratory in personnel, equipment, or in a laboratory's location that might alter or impair analytical capability and quality.

3.3.4 Announced and unannounced visits

The accrediting authority, at its discretion, may conduct either unannounced or announced on-site assessments. The accrediting authority is not required to provide advance notice of an assessment.

3.4 PRE-ASSESSMENT PROCEDURES

3.4.1 Assessment planning

A good assessment begins with planning, which should commence well before the assessment team visits the laboratory. Planning is the means by which the lead assessor identifies all the required activities to be completed during the assessment process. Planning includes conducting a thorough review of NELAP and/or State records pertaining to the laboratory to be inspected. This may save time because familiarity with the operation, history, and compliance status of the laboratory increases the efficiency and focus of an on-site visit.

Pre-assessment activities include: deciding the scope of the assessment; reviewing NELAP/State information; providing advance notification of the assessment to the laboratory, when appropriate; obtaining any security clearances which may be necessary; coordinating the assessment team; and gathering assessment documents. Section 3.4.5 discusses Confidential Business Information (CBI) issues.

3.4.2 Scope of the assessment

The first step in the assessment planning process is deciding what type of assessment will be conducted. The assessment may be a general one to determine the capability of the laboratory to perform environmental testing or a specific examination of a certain area of testing. The assessment must include both an appraisal of the laboratory's operations and a review of the appropriate records. The assessment for a field of testing must cover all of the tests for which the laboratory seeks accreditation.

3.4.2.1 Laboratory assessments

A laboratory assessment should review the ability of the lab to conduct environmental testing. The examination of the systems, processes and procedures of the laboratory should give a general sense of its past and present capabilities to perform work of known and documented quality. During a laboratory assessment, the assessment team may identify a number of samples or a recently completed or on-going project and evaluate to what extent the tests are being conducted according to NELAC standards.

3.4.2.2 Records review

The purpose of a records review is to determine whether the testing laboratory has maintained necessary documentation of data and other information to technically substantiate reports previously issued.

During a records review, the assessment team will conduct an overall audit of data and will compare data with submitted reports to determine whether the data were collected, generated, and reported following the NELAC standards.

3.4.3 Information collection and review

Prior to initiating an on-site assessment, the assessment team shall make determinations as to which laboratory records they wish to review prior to the actual site visit. These records, from the files of the accrediting authority, the national laboratory accreditation database, or the laboratory itself may include, but are not limited to:

a) Copies of previous assessment reports and proficiency testing sample results;
b) General laboratory information such as laboratory submitted self-assessment forms, SOPs and Quality Assurance Plan(s);
c) Official laboratory communications and associated records with appropriate accrediting authority staff.
d) Available documents from recipients of reports from the laboratory;
e) The laboratory's application for accreditation;
f) The existing program regulations and special requirements that apply to the areas for which accreditation is sought (i.e. security clearances, radioactive exposure protocols, etc.); and
g) The most recently approved analytical methods for the tests for which the laboratory has requested accreditation.

3.4.4 Assessment documents

Documents necessary for the assessment and which may need to be provided to the laboratory management or staff should be assembled before the assessment, whenever possible. The lead assessor should obtain copies of the required assessment forms, including the NELAC-approved checklist(s). Other types of documents that may be required include:

- Assessment Confidentiality Notice;
- Conflict of Interest Form;
- Assessor Credentials;
- Assessment Assignment(s);
- Assessment Notification Letter;
- Attendance Sheet(s) (opening and closing conference); and,
- Assessment Appraisal Form.

In addition, the lead assessor should be able to provide information about how to obtain copies of documents and materials associated with an assessment from the accrediting authority.

3.4.5 Confidential Business Information (CBI) considerations

During on-site assessments, it is likely that the accrediting agency staff will come into possession of some confidential business information, such as rates charged different clients, trade secrets, including some formulations of reagents etc. that may be part of the assessment information but which must be protected from unauthorized release. The type of information that may be considered confidential business information is defined in Title 40, Code of Federal Regulations, Part 2. For this data to be adequately protected, certain actions are required immediately prior to or at the onset of the on-site assessment.

NELAC standards protect Confidential Business Information (CBI) from disclosure. CBI includes trade secrets (including process, formulation, or production data) and certain financial information, the uncontrolled disclosure of which could cause damage to a laboratory's competitive position.

A lead assessor must present notice to laboratory representatives of their right to claim data at the laboratory as CBI and such claims are frequently made. Because the assessment team is very likely to require access to CBI before (i.e., while preparing for an assessment), during, and after an assessment, the lead assessor must be knowledgeable of NELAP/State procedures governing access to, handling of, and disclosure of CBI. The lead assessor and others who may use the information must have CBI access authorization, since only authorized individuals may have access to CBI. A CBI-cleared lead assessor may obtain access to CBI documents from the accrediting authority by requesting access to the information from the appropriate official.

Whether or not it is anticipated that CBI documents will be collected during an assessment, the lead assessor must provide a NELAP/State assessment confidentiality notice to the responsible laboratory official at the beginning of the assessment. This notice informs laboratory officials of their right to potentially claim part of the assessment data as CBI. The lead assessor should be familiar with the procedures for asserting a CBI claim and the standards that the claimed information must meet.

The lead assessor must take custody of all CBI documents before leaving the laboratory, and must maintain them in custody, using all proper procedures and safeguards, until they can be received by the accrediting authority.

3.5 ASSESSMENT SCHEDULE/FORMAT

3.5.1 Length of assessment

The length of an on-site assessment will depend upon a number of factors such as the number of tests for which a laboratory desires accreditation, the number of assessors available, the size of the laboratory, the number of problems encountered during the assessment, and the cooperativeness of the laboratory staff. The assessor body should assign an adequate number of assessors to complete the assessment within a reasonable period of time. Assessors must strike a balance between thoroughness and practicality, but in all cases must determine to what effect the laboratories' operations meet NELAC standards.

3.5.2 Opening conference

Arrival at the facility should normally occur during established working hours. The responsible laboratory official(s) should be located as soon as the assessment team arrives on the premises.

A laboratory's refusal to admit the assessment team for an assessment will result in an automatic failure of the laboratory to receive accreditation or loss of an existing accreditation by the laboratory, unless there are extenuating circumstances that are accepted and documented by the accreditation authority. The team leader must notify the accrediting authority as soon as possible after refusal of entry.

An opening conference must be conducted and shall address the following topics:

a) the purpose of the assessment;
b) the identification of the assessment team;
c) the tests that will be examined;
d) any pertinent records and operating procedures to be examined during the assessment and the names of the individuals in the laboratory responsible for providing the assessment team with the necessary documentation;
e) the roles and responsibilities of key managers and staff in the laboratory;
f) the procedures related to Confidential Business Information;
g) any special safety procedures that the laboratory may think necessary for the protection of the assessment team while in certain parts of the facility (under no circumstance is an assessment team required or even allowed to sign any waiver of responsibility on the part of the laboratory for injuries incurred by a team member during an inspection to gain access to the facility);

h) the standards that will be used by the assessors in judging the adequacy of the laboratory operation;
i) confirmation of the tentative time for the exit conference;
j) provision of the assessment appraisal form to the responsible laboratory official (to be submitted to NELAP and the accrediting authority); and
k) discussion of any questions the laboratory may have about the assessment process.

3.5.3 Records review

Records will be reviewed by assessment team members for accuracy, completeness and the use of proper methodology for each test and analyte to be evaluated.

A minimum record set that must be examined as part of a accreditation assessment includes;

a) application for accreditation from the laboratory;
b) previous assessment results and reports including proficiency testing results;
c) laboratory management structure and chains of responsibility (e.g. organizational charts);
d) qualifications statements of all key staff involved in the analysis or reporting of results for which accreditation has been requested and a matching of the staff qualifications with the statements submitted with the applications;
e) quality assurance plan(s) for the laboratory;
f) standard operating procedures and methodologies for each parameter for which accreditation is sought;
g) maintenance and calibration records of specific pieces of laboratory equipment separate and apart from that encompassed in analyte specific records;
h) procedures for the make-up and calibration of stock solutions and standard reagents;
i) origins, purities, assays and expiration dates of primary standards, analytical reagents and standard reference materials;
j) records associated with method-specific QA\QC requirements;
k) the specific records associated with the initial method validation study in the laboratory which must be examined in detail with the historical calibration data;
l) records associated with the methods used to estimate precision and accuracy in general for specific analyses;
m) sample receipt and handling documentation;
n) proficiency testing sample receipt and handling procedures;
o) information about the proficiency testing providers;

p) records of any internal audits conducted or corrective actions taken by the laboratory itself; and
q) the report of the laboratory's annual management review.

The laboratory must mark all confidential information. The lead assessor must handle it as required by appropriate laws and regulations. All other information for all aspects of application, assessment and accreditation of laboratories is considered public information. If the laboratory requests that information other than noted above is confidential, the information should be treated as confidential until a ruling can be made by the accreditation authority.

3.5.4 Staff interviews

As an element of the assessment process, the assessment team may evaluate an analysis regimen by requesting that the analyst normally conducting the procedure give a step-by-step description of exactly what is done and what equipment and supplies are needed to complete the regimen. Any deficiencies shall be noted and discussed with the analyst. The deficiencies will also be discussed in the closing conference.

The assessment team members shall have the authority to conduct interviews with any/all staff. Calculations, data transfers, calibration procedures, quality control/assurance practices, adherence to SOPs and report preparation shall be assessed for each test with the appropriate analysts(s).

3.5.5 Closing conference

The assessment team must meet with representative(s) of the laboratory following the assessment for an informal debriefing and discussion of findings with the possible exception of any issues of improper and/or potentially illegal activity which may be the subject of further action. It should be noted that the assessment team in no way limits its ability to identify additional problem areas in the final report should it become necessary.

In the event the laboratory disagrees with the findings of the assessor(s), and the team leader adheres to the original findings, the deficiencies with which the laboratory takes exception shall be documented by the team leader and included in the report to the accreditation authority for consideration. The accrediting authority will make the final determination as to the validity of the contested elements.

The assessment team should inform the laboratory representative(s) that an assessment report encompassing all relevant information concerning the ability of the applicant laboratory to comply with the accreditation requirements is forthcoming.

3.5.6 Follow-up procedures

The accrediting authority will issue the assessment report to the applicant laboratory outlining any area of deficiency. The applicant laboratory must then submit a plan of corrective action and supporting documentation that meet applicable NELAC standards and address all deficiencies noted in the report not later than thirty days from when the report is received (see Section 4.1.4).

3.5.7 Assessment closure

After reviewing the assessor's report(s) and any completed corrective action(s) reported by the laboratory, the accrediting authority will make the determination of the accreditation status for a laboratory.

If the deficiencies listed are substantial or numerous, an additional on-site assessment may be conducted before a final decision for accreditation can be made.

3.6 STANDARDS FOR ASSESSMENT

3.6.1 Assessor's manual

The NELAC will develop a manual(s) for on-site assessors to help ensure that on-site assessments are performed in a uniform, consistent manner. The manual(s) will be provided when assessors take the NELAC required training (Section 3.2.1) and will serve as guidance for on-site assessment personnel.

The manual(s) provided to on-site assessors should include instructions for evaluating the following items:

a) Size, appearance, and adequacy of the laboratory facility;
b) Organization and management of the laboratory;
c) Qualifications and experience of laboratory personnel;
d) Receipt, tracking and handling of samples;
e) Listing/inventory, condition, and performance of laboratory instrumentation and equipment;
f) Source, traceability and preparation of calibration/verification standards;

g) Test methods (Including the adequacy of the laboratory's standard operating procedures as well as confirmation of the analyst's adherence to SOPs, and the analyst's proficiency with the described task);
h) Data reduction procedures, including an examination of raw data and confirmation that final reported results are derived from raw data and original observations;
i) Quality assurance/quality control procedures, including adherence to the laboratory's quality assurance plan and adequacy of the plan;
j) General health and safety procedures as they relate to good laboratory practices; and
k) Laboratory waste disposal procedures.

3.6.2 Assessor's role

When performing an on-site laboratory assessment, the assessor must appraise each of the areas listed in Section 3.6.1 and perform a thorough assessment of the records for each of the tests for which accreditation has been requested.

The on-site assessor should use a variety of tools in the assessment process. The experience of the assessor, his/her observations, interviews with laboratory staff, and examination of SOPs, raw data, and the laboratory's documentation all play important roles in the assessment. The accreditation of a particular laboratory will depend to a large extent on the assessment team's findings and recommendations. Much of the on-site assessment will depend upon the assessor's observations of existing conditions. The recommendation not to accredit a laboratory, or to change a laboratory's accreditation status, must be based on factual information and not upon subjective evaluations. Therefore, it is crucial that the on-site assessor have a clear understanding of the laboratory's procedures and policies and that the assessor document any deficiencies in the report of the on-site assessment.

The assessment team must use specific documentation in its reporting of deficiencies. The assessor should discuss any deficiencies with the laboratory's management at the exit conference.

During the assessment, sufficient information may become available to suspect that a particular person has violated an environmental law or regulation, such as knowingly making a false statement on a report. This information should be carefully documented since further action may be necessary. In the event that evidence of improper and/or potentially illegal activities have or may have occurred, the assessment team should present such information to the accrediting authority for appropriate

action(s). These issues, at the discretion of the accrediting authority, may or may not be subjects or issues of the closing conference. However, the assessor should continue to gather the information necessary to complete the accreditation assessment.

3.6.3 Checklists

Standardized checklists must be used for the on-site assessment. The use of checklists does not replace the need for assessor observations and staff interviews, but is another tool which assists in conducting a thorough and efficient assessment. A checklist is not a substitute for assessor training and experience.

Note: It is anticipated that standardized checklists will be developed or adopted by NELAC's On-Site Assessment Committee for the assessor's review of test methods.

3.6.4 Assessment standards

The areas to be evaluated in an on-site assessment shall include:

a) Size, appearance, and adequacy of the laboratory facility;
b) Organization and management of the laboratory;
c) Qualifications and experience of laboratory personnel;
d) Receipt, tracking and handling of samples;
e) Quantity, condition, and performance of laboratory instrumentation and equipment;
f) Preparation and traceability of calibration standards;
g) Test methods (Including the adequacy of the laboratory’s standard operating procedures as well as confirmation of the analyst(s) adherence to SOPs, and the analyst(s) proficiency with the described task);
h) Data reduction procedures, including an examination of raw data and confirmation that final reported results can be traced to the raw data/original observations;
i) Quality assurance/quality control procedures, including adherence to the laboratory's quality assurance plan(s) and adequacy of the plan(s);
j) General health and safety procedures as they relate to good laboratory practices; and
k) Laboratory waste disposal procedures.

These areas should be evaluated against the standards detailed in Section 5, Quality Systems, of the NELAC Standards. Additional information on the process for evaluating these areas can be found in the Assessors Manual (Section 3.6.1).

3.7 DOCUMENTATION OF ON-SITE ASSESSMENT

3.7.1 Checklists

The checklists used by the assessors during the assessment shall become a part of the permanent file kept by the accrediting authority for each laboratory.

3.7.2 Report format

The final site visit report shall be written to contain a description of the adequacy of the laboratory as it relates to the assessment standards in Section 3.6.4. Assessment reports should be generated in a narrative format. Deficiencies must be addressed at a minimum. Documentation of existing conditions at the laboratory should be included in each report to serve as a baseline for future contacts with the facility.

Assessment reports will contain:

a) Identification of the organization assessed (name and address),
b) Date of the assessment,
c) Identification and affiliation of each assessment team member,
d) Identification of participants in the assessment process,
e) Statement of the objective of the assessment,
f) Summary,
g) Assessment findings (deficiencies) and requirements, and
h) Comments and recommendations.

The Findings and Requirements Section must be referenced to a NELAC standard so that both the finding (deficiency) is understood and the specific requirement is outlined. The team leader shall assure that the results within the final report conform to established standards for the evaluated parameters.

The Comments and Recommendations Section can be used to convey recommendations aimed at helping the laboratory improve.

3.7.3 Distribution

The accrediting authority shall be recognized as having the responsibility for the distribution of the assessment reports. The assessment team leader shall compile, edit and submit the final report to the accrediting authority.

3.7.4 Report deadline

No more than thirty (30) days shall elapse from the completion of the assessment until the report is completed by the accrediting authority and copies are transmitted to the laboratory and the National Accreditation Database. An exception to this deadline may be necessary in those circumstances where an investigation or other action has been initiated by the accrediting authority, in which case the laboratory must be notified.

3.7.5 Release of report

On-site assessment reports should be released initially by the accrediting authority only. The reports will be released to the responsible laboratory official(s). The assessment report shall not be released to the public until findings of the assessment have been finalized, all Confidential Business Information has been stricken from the report in accordance with prescribed procedures, and the report has been provided to the laboratory.

In accordance with the Freedom of Information requirements, any documentation adjudged to be proprietary, financial and/or trade information, or relevant to an ongoing enforcement investigation, will be considered exempt from release to the public.

3.7.6 Record retention time

Copies of all assessment reports, checklists, and laboratory responses must be retained by the assessors and the accrediting authority for a period of at least ten years, or longer if required by specific State or Federal regulations.